*Results:* The Wallstent were successfully implanted in 36 pts. In one patient, there was a stent delivery failure. There were two retrieval failures of stent delivery catheter and these two pts were sent to surgery. Angiographic and IVUS data are shown below.

| | Pre MLD (mm) | Post MLD (mm) | Post min. CSA ($mm^2$) | Stent length (mm) |
|---|---|---|---|---|
| Stent | 0.91 | 3.29 | 6.7 | 63.5 |

MLD, minimum lumen diameter; CSA, cross sectional area

There was one subacute stent thrombosis occurring 4 days after the procedure due to uncovered distal dissection. Long-term follow-up data will be available at the time of presentation.

*Conclusion:* The use of a single Wallstent to cover long lesions or multiple lesions in coronary arteries or bypass venous grafts is feasible and can be done with good immediate angiographic, IVUS and clinical results.

3:00

### 711-5 Initial Experience of the ACS Multi Link Stent: Comparison With the Palmaz-Schatz Stent Based on Lesion Matching

Yoshiki Nakano, Hideyuki Nosaka, Takeshi Kimura, Masakiyo Nobuyoshi. *Kitakyushu, Kokura Memorial Hospital, Japan*

From Apr. to Aug. 1995, ACS stent implantation was performed in 40 patients (M/F = 31/9, age 67.6 ± 7.3) with 46 lesions. (LAD 14, RCA 26, LCX 4, SVG 2, restenotic lesions 26%, multiple stents 7%, unplanned use 43%) Diameter of stent was 3.0 mm in 20 lesions, 3.25 mm in 4 lesions, and 3.5 mm in 19 lesions. Primary success was achieved in 43 lesions (93%). In 6 lesions, ACS stent implantation was successful after delivery failure of the Palmaz-Schatz (P-S stent. There was no in-hospital major complication except for one episode of subacute stent thrombosis resulting in non-Q wave myocardial infarction. Acute luminal outcome was compared with that of P-S stent, in lesions matched for reference diameter (≤ 0.3 mm), and minimal lumen diameter (MLD) (≤ 0.1 mm). Quantitative angiographic analysis was performed by using the CAAS II system.

| | Lesion length (mm) | Reference (mm) | MLDpre (mm) | MLDpost (mm) |
|---|---|---|---|---|
| ACS | 7.45 ± 2.94 | 3.08 ± 0.62 | 1.12 ± 0.50 | 2.61 ± 0.38 |
| P-S | 7.95 ± 3.69 | 3.10 ± 0.58 | 1.10 ± 0.48 | 2.55 ± 0.42 |

In conclusion, MLD at least comparable to that after the rigid P-S stent was achieved by using more flexible ACS Multi Link stent with acceptably low complication rate.

3:15

### 711-6 The Nitinol Self Expanding Coronary Stent: Acute Angiographic and Clinical Results of the Pilot Registry

Rafael Beyar, Ariel Roguin, Ehud Grenadier, Walter Markiewicz. *Rambam Hospital, and the Technion-IIT, Haifa, Israel*

We provide here the first report on human implantations of the self expanding nitinol coronary stent in 20 consecutive patients (pts) treated between Jan. and Aug. of 1995 (one pt had a 24 mm stent implanted in Aug., 1993). The initial five pts had chronic total occlusion (RCA-3; LAD-2) and required the use of 11 stents; 15 pts were treated for suboptimal results or dissection (RCA-5; LAD-9; LCX-1), requiring 20 stents. Double sequential stenting covering a 30 mm length was performed in 9 pts with excellent conformability to the vessel curvature. Within-stent balloon dilatations to the nominal stent size at pressures ranging between 10 and 14 atm were performed in all cases. No stent migration was observed during balloon or stent passage. The balloon-gain in minimal luminal diameter was 0.95 ± 0.91 mm; the stent-gain was 0.33 ± 0.66 mm; and the total, balloon-assisted stent-gain 0.57 ± 0.75 mm. There were no procedural complications without death Q wave MI or emergency CABG. In one pt a large spiral dissection not covered entirely by the stent caused acute occlusion, successfully treated with further stenting. Subacute thrombosis occurred in one pt with total occlusion due to dissection at a portion distal to the stent, and treated successfully and uneventfully with further stenting. Therefore, our preliminary experience suggests that the stent provides adequate arterial support through its intrinsic self expanding properties aided by balloon inflation, is safe and effective in the treatment of suboptimal results, is well adjusted to curved arteries, and can be easily implanted sequentially to cover long lesions.

## 712 Angioplasty: Clinical Trials

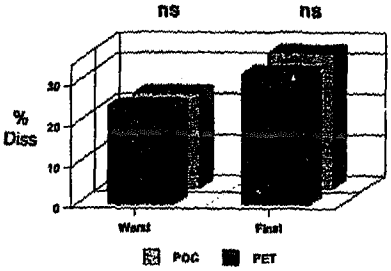
Monday, March 25, 1996, 2:00 p.m.–3:30 p.m.
Orange County Convention Center, Room 414C

2:00

### 712-1 Compliance of Balloon Material Does Not Effect Angiographic Dissection Rate. Results From the *CRAC* (Compliant Related Acute Complication) Study

J. David Talley, James Blankenship, Steven Werns, Artur Spokojny, Charles Landau, H.V. Anderson, Harvey White, Richard Bach, Robert Siegal, Mitchell Krucoff, Russell Raymond, Stafford Warren, Joe Bissett, Millie Rawert, Wendy Etka, Mitchell Hope, Robert Vogel. *Univ of Arkansas, Little Rock, AR*

The relationship between the compliance of PTCA balloon material to angiographic dissection (Diss) rate is a mystery. *CRAC* is a prospective randomized trial of PET (non-compliant) POC(most compliant) balloon material and angiographic diss rate in 1250 patients undergoing de novo native vessel PTCA at 33 centers. The 1º endpoint was worst angiographic dissection, 2º endpoint was final dissection (NHLBI type) determined in a core laboratory by consensus of 2 of 3 MD's blinded to balloon material randomization.




*In conclusion:* This trial demonstrates that balloon compliance is not related to angiographic dissection.

2:15

### 712-2 One-Year Frequency of Restenosis After PTCA in EAST

Xue-Qiao Zhao, B. Greg Brown, Lynn A. Hillger, Spencer B. King III. *EAST Angiographic Core Lab, Univ. of Washington, Seattle, WA; Emory Univ. School of Medicine, Atlanta, GA*

The Emory Angioplasty vs. Surgery Trial (EAST) randomized pts with multivessel disease to an initial strategy of PTCA or CABG. Of 198 pts who were randomized to PTCA, 155 had successful initial angioplasty without in-hospital complication or CABG and completed one-year angiographic follow-up (F/U). Restenosis (RS) was defined as a luminal diameter narrowing ≥ 50%S. Of 352 lesions were dilated at baseline, 154 (44%) had ≥ 50% restenosis and 58 (16%) had severe (≥ 70%) restenosis during one-year F/U. 44 (28%) pts required at least one additional revascularization procedure (PTCA or CABG) due to recurrent symptoms and restenosis, an average of 4 ± 2 months after initial dilation (ProRS). 62 (40%) pts had some restenotic lesions but did not receive any additional procedure during one-year F/U (NoProRS). 49 (32%) pts were free of both additional procedures and angiographic restenosis at one year (NoRS). ProRS, NoProRS and NoRS were compared in terms of number of index lesions dilated, per pt, average disease severity per dilated lesion at pre- and post-PTCA and proportion of pts whose worst restenosis was moderate (50–69%) or was severe (≥ 70%).

*Results:*

| | Pts N | Pts % | Baseline #Les dilated | Baseline % S per les | Post-PTCA % S per les | Post-PTCA Minimal diameter | During F/U Worst 50–69% | During F/U RS ≥ 70% |
|---|---|---|---|---|---|---|---|---|
| ProRS | 44 | 28 | 2.2 ± 0.7* | 73 ± 10 | 39 ± 14* | 1.6 ± 0.4* | 10 | 34† |
| NoProRS | 62 | 40 | 2.5 ± 0.8 | 73 ± 11 | 41 ± 10 | 1.6 ± 0.4 | 45 | 17 |
| NoRS | 49 | 32 | 2.0 ± 0.8 | 72 ± 11 | 36 ± 10 | 1.8 ± 0.4 | 0 | 0 |

*$p < 0.05$ by one-way ANOVA, †$p < 0.001$ by Chi-square test.

*Conclusions:* In EAST, 68% of pts and 44% of lesions developed restenosis during one-year F/U. The per-pt likelihood of restenosis after multilesion angioplasty in the first year was not associated with baseline disease severity.

MONDAY ORAL